



UNITED STATES PATENT AND TRADEMARK OFFICE

ST

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,569	10/26/2001	Esha A. Gangolli	21402-191 (CURA 491)	8659

7590 08/24/2005

Jenell Lawson
Intellectual property CuraGen corporation
555 Long Wharf Drive
New Haven, CT 06551

EXAMINER

PAK, MICHAEL D

ART UNIT	PAPER NUMBER
----------	--------------

1646

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/055,569	GANGOLLI, ESHA A.	
	Examiner	Art Unit	
	Michael Pak	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-10,12-14,30,33 and 42-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-10,12-14,30,33 and 42-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6-13-05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Amendment filed June 13, 2005 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed June 13, 2005, have been fully considered but they are not found persuasive.

Claim Rejections - 35 USC § 101

4. Claims 5-10, 12-14, 30, 33, and 42-48 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

The reason for the rejection has been set forth in the previous office action.

Applicants argue that the expression of Nov8 in cancer cell lines provide substantial utility as a marker for cancers. However, the expression studies show high expression in cell line SK-N-AS as well as in a breast cancer cell line which are research tool cell line and does not appear to have any therapeutic nexus to a specific cancer treatment. Furthermore, the function of the Nov8 is not known and is an orphan protein and thus further experimentation is required to determine the function of the

Art Unit: 1646

Nov8 prior to any types of cancer treatment is possible. Thus the Nov8 lacks substantial utility.

Claims 5-10, 12-14, 30, 33 and 42-48 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

5. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The reason for the rejection has been set forth in the previous office action.

Applicants argue that the structure of the polynucleotide is known because it is an elementary exercise for one of skill in the art to define the nucleic acid. However, claim 10 encompasses a large genus of nucleic acid which cannot be envisioned by one skilled in the art because many molecules hybridize under even the most stringent conditions. With so many molecules one skilled in the art cannot envision without the known function for the encoding orphan protein which molecules is being claimed. Claims 10 encompass an isolated nucleic acid encoding polypeptide variants and fragments of proteins without functional limitations. However, the essential feature of

Art Unit: 1646

the invention is the polypeptide channel subunit of SEQ ID NO:20, and one of skilled in the art cannot envision the full genus of molecules of the claimed polypeptide molecules. The claims encompass variants whose structure is not known or other variant proteins with different function from SEQ ID NO:20 taught in the specification. Claimed protein variants encompass a large genus of proteins or channels which are alleles or variants whose function has yet to be identified from different species of animal because the structure of the newly identified naturally occurring protein is not known. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification.

Priority

6. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, the applications upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 5-10, 12-14, 30, 33 and 42-48 of this application for the reasons provided above. See MPEP 706.02.

Claim Rejections - 35 USC § 102

7. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Stripp et al. (J. Cell Biol., 1994).

Stripp et al. discloses a nucleic acid encoding a protein which is 83% best local similarity to the claimed polypeptide of SEQ ID NO:20 (pages 152-153). Meadows et al.

Art Unit: 1646

discloses a composition comprising the polypeptide with a carrier (page 17). Stripp et al. discloses hybridization with the nucleic (pages 153-157).

Applicants argue that claim 10 pertains to a sequence which hybridizes (i.e. the complement or reverse transcript) to a nucleic acid sequence that encodes applicant's protein SEQ ID NO:20. However, claim 10 is more generic than applicant's subgenus of complement or reverse transcript because many nucleic acid molecules which are not identical throughout but have regions of identity will hybridize under stringent conditions. Since the USPTO is not able to perform experiments and nucleic acid which have high sequence identity will hybridize under the most stringent conditions, the nucleic acid of Stripp et al. will hybridize under the given conditions inherently.

8. No claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

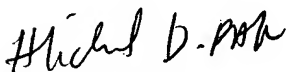
Art Unit: 1646

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached on 8:00 - 2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 571-272-082929. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.


Michael Pak
Primary Examiner
Art Unit 1646
20 August 2005